



Standards Alliance Quarterly Report 2017 – Q4

Period of Performance: October 1 – December 31, 2017

INTRODUCTION

The following report contains a summary of the major activities completed and outcomes achieved of the Standards Alliance, a public-private partnership between the American National Standards Institute (ANSI) and the U.S. Agency for International Development (USAID). The enclosed report contains a summary of all activities completed in the fourth quarter of 2017.

The <u>Standards Alliance</u> was announced by USAID in November 2012 as a new funding facility designed to provide capacity building assistance to developing countries, specifically related to implementation of the WTO Technical Barriers to Trade (TBT) Agreement. In May 2013, USAID and ANSI entered into a public-private partnership, which will coordinate subject matter experts from throughout the private sector-led U.S. standardization system in the delivery of training and other technical assistance to interested Standards Alliance countries.

SUMMARY OF ACTIVITIES COMPLETED DURING PERIOD OF PERFORMANCE

This period of performance was dedicated primarily to implementation of activities described in the country-specific work plans in Mozambique, Latin America and Vietnam; as well as planning for first quarter 2018 activities. A general summary of these activities, according to their country or region is listed below.

General Program Management/Promotion

Outreach to engage partner agencies, organizations, and countries

ANSI updated the Standards Alliance website including the dates and locations of project activities and trainings conducted in partnership with other agencies and organizations, as well as materials from past events. This also included the addition of a West Africa page reflecting the Trade Africa expansion and other new features. Also through regular email correspondence, ANSI updated its members and U.S. government stakeholders.

Colombia, Mexico, Peru and CAFTA-DR

 Advanced Medical Technology Association (AdvaMed) Regulatory Coherence, Good Regulatory Practices and Capacity Building Project in Latin America- (Added to Year 4 Annual Plan in Q1) During the fourth quarter of 2017, AdvaMed continued implementation of its work plan with medical device regulators in Latin America. AdvaMed and ANSI participated in ongoing meeting at the Americas Business Dialogue (ABD) and its regulatory Working Group, led by the Center for Global Regulatory Cooperation at the U.S. Chamber of Commerce, together with the ABD secretariat and the inter- American Development Bank (IDB). The ABD plenary endorsed draft recommendations including those for Good Regulatory Practices (GRP) based on the Standards Alliance Tier 1 Phase 1 work, at its October 5-6 meeting in Miami. The IDB is submitting these recommendations to the Summit of the Americas CEOs and Leaders as the consensus position of the Western Hemispheric private sector, encouraging implementation of GRP policies across the Americas during their April 12-14, 2018 meetings in Lima, Peru. A Tier 1 Phase 4 Regulatory Coherence webinar is being considered for April, 2018. The webinar is intended for representatives from nine Latin American countries including Colombia, Costa Rica, Mexico, Peru, El Salvador, the Dominican Republic, Argentina, Brazil, Ecuador and the Organization for Economic Cooperation and Development (OECD).

In December, AdvaMed worked to finalize a detailed schedule and agenda for a proposed INVIMA delegation visit to the U.S., in January 14-19, 2018. On Dec 13-14, Jeff Weiss and Renato Perez of Venable held meetings in Bogotá, Colombia and completed significant portions of the Tier 1 Phases 2 and 3 work for Colombia. Venable met with the Asociación Nacional de Empresarios de Colombia – Camera de Dispositivos Médicos (ANDI-CDMIS) and some of its member companies including Marisol Sánchez González (ANDI), Natalia Valbuena (Medtronic), Adriana Caicedo (Roche) and Andrea Cataño (Baxter), who provided additional information and validation of the Tiers 1 and 2 Phase 2 information. On December 19, Weiss and Perez held meetings in San Jose, Costa Rica, completing significant portions of the Tier 1 Phases 2 and 3 work for Costa Rica.

Meetings are now being planned for the Tier 1 Phase 2 and 3 bilateral engagement with the Regulatory Coherence authorities in Mexico City and Lima during the February-March, 2018 timeframe. Planning continued with Pan American Health Organization (PAHO) for a follow-up Tier 2 Phase 4 workshop. The workshop will take place in February 2018 in Mexico City in conjunction with the next COFEPRIS (the Mexican health authority) Center of Excellence event.

<u>Indonesia</u>

IAPMO Water for Indonesia Now project – (Year 4 Annual Plan #7)

In Q4, IAPMO was appointed as the third- party verification agency for the Green Product Council of Indonesia. Their first inspection took place in December and upon receiving satisfactory results from IAPMO's verification activities, the product will receive Green Label Indonesia. Q4 also marked a major milestone for the plumbing industry in Indonesia with the formation of the Indonesia Plumbing Association (APIN).

APIN has 9 founding members including Kohler, American Standard, Fluidmaster and Roto Rooter. IAPMO Group Indonesia volunteers as the secretariat for APIN.

During Q4, IAPMO also visited the Ministry of Public Work to explore partnership opportunities to incorporate SNI 8153:2015 into their permit process and inspection. IAPMO continued implementation of the Community Plumbing Challenge 2017 program (CPC2017) and organized a demonstration project which achieved a major milestone in Q4. The purpose of the project was to highlight the impact of the new plumbing standard on community level construction projects and the importance of training to the new standards. The project was delivered in three parts: a 'Design Week' in August 2017, 'Construction Week 1' in November 2017, and 'Construction Week 2' in March 2018.

For Design Week, a team of plumbers, plumbing engineers, and architects from Indonesia, India, Australia, and the United States surveyed Sekolah Dasar Negeri (SDN) Cicau 02 in Cicau Village, Cikarang, to come up with a sustainable plan for improving the school's water supply, wastewater management, and hand-washing situation. They also presented a series of games and activities to teach the schoolchildren about personal hygiene and hand-washing, demonstrating the link to both plumbing and design. For Construction Week 1, the International Team consisted of plumbing professionals — plus trades including bricklaying, welding, and carpentry — from Indonesia, Australia, the United States, and Singapore. The team renovated the existing toilet facilities in one of the buildings at SDN Cicau 02, increasing the number of toilets from two to four; built a new hand-washing area outside the renovated toilets; installed two new elevated water tanks for improved water supply; and installed a new wastewater system. Education also played a key role in CPC2017, as a team representing IWSH collaborated with the Cikarang District Health Clinic to present a Public Health Awareness Showcase on Nov. 11th. More than 100 local residents received free health checkups, and approximately 65 prescriptions were given out for various medical conditions.





IAPMO recognized that working with the various communities continues to help develop not only the cultural awareness around hygiene practices, but —more

importantly — behavioral aspects when it comes to sanitation. The events of Nov. 9-15 represent phase one of Construction Week. For phase two, which will take place in spring 2018, an expanded team of local apprentices will renovate the toilets in the second building as part of a CPC2017 "legacy" project.

<u>Jordan – Middle East and North Africa (MENA)</u>

IAPMO engagement with JSMO, MPWH, and RSS (Added to Year 4 Annual Plan in Q1)

As part of the USAID-Standards Alliance funded Middle East Project, IAPMO continues to work with staff officials from the Jordan Standards and Metrology Organization (JSMO), the Ministry of Public Works and Housing (MPWH), the Jordanian Royal Scientific Society (RSS), and the Water Authority of Jordan to define the scope of our partnership and to outline the funding requirements. During this quarter, IAMPO joined the Jordanian National Building Council (JNBC), Water Authority of Jordan (WAJ), and Jordan Standards and Metrology Organization (JSMO) in signing a memorandum of understanding (MOU) to enhance water/ sanitation infrastructure in the kingdom through the continued development and enforcement of plumbing codes and standards.



Rooted in their shared understanding of the importance of standards in developing water and sanitation related infrastructure, the signees agree to cooperate via the MOU on such goals as:

- Recognize and promote the value of the most recent edition of the Uniform Plumbing Code (UPC) to update Jordan's current plumbing code, which is based on an older version of the UPC
- Promote the development of a skilled workforce that is capable of designing, building, maintaining, enforcing and inspecting the quality of water systems in buildings that Jordan desires
- Recognize the important role international standards play in developing a conformity assessment scheme for plumbing products that will enhance manufacturing in Jordan and promote the trade of goods certified to safety and efficiency standards

The signing of the MOU marks the consolidation of a true partnership with IAPMO. This is an opportunity to further develop the Jordanian plumbing code and national standards in addition to product certification and personnel certification of plumbers and inspectors on plumbing systems that can assist Jordan in contributing to solutions dealing with water scarcity.

Specifically, IAPMO pledged to work with JSMO and other government stakeholders in mandating water efficient plumbing regulations and product standards, provide technical assistance in developing conformity assessment schemes and processes that meet international best practices, provide the most recent edition of the UPC to JNBC and JSMO to officials updating Jordan's codes, and assist in the development of personnel certification criteria for a skilled workforce and competent inspection officials. During Q1 2018 a more detailed work plan will be put together addressing future deliverables, milestones and timelines necessary to achieve the objectives of the MOU.

Mozambique

Planning for Workshop on Good Regulatory Practices (GRP) (Year 5 Annual Plan #11)

During the fourth quarter, ANSI began preparations for a GRP workshop in Mozambique in 2018. ANSI is working with INNOQ and the Government of Mozambique to finalize dates for this event. INNOQ and GOM are in the process of finalizing a government-wide, 5-year strategic plan. This plan will guide future work and is expected to be completed by late January 2018.

<u>Peru</u>

 Planning for ASME Advanced Manufacturing Workshop (New addition to Year 4 Annual Plan)

The Standards Alliance and the American Society for Mechanical Engineers (ASME) are currently planning a two-day workshop designed to provide knowledge and tools required to participate in the advanced manufacturing industry. The workshop was set to take place in November 2017 but was postponed to take place on April 11-12, 2018 in Lima. EngineZone has been contracted by ASME to deliver and finalize the workshop details. The workshop will include details on the latest technological advancements currently being incorporated in international standards. Speakers will include ASME's subject matter experts (SMEs) who are highly qualified and possess knowledge of international standards used in the Advanced Manufacturing Industry, specifically Geometric Dimensioning and Tolerancing (GD&T) applications including ASME Y14.5, ASTM F42, ISO/TC 261, ASME B.46, and ASME Y14.46.

Southern Africa

 Standards Alliance Participation in ARSO CACO Meeting in Namibia (Year 5 Annual Plan #8)

The Standards Alliance sponsored U.S. participation and training on Sustainable Agriculture standards at the October African Organization for Standardization (ARSO) Conformity Assessment Committee (ARSO CACO) meeting in Swakopmund, Namibia. Mike Arny of Leonardo Academy traveled to the ARSO CACO and provided a presentation covering the components and usage of the American National Standard for Sustainable Agriculture (ANSI/LEO-4000) and elaboration on U.S. sustainable agriculture standards.

West Africa (Cote D'Ivoire, Ghana, and Senegal)

Creation of ANSI-ASSESS FY2018 Work plan and Budget

ANSI worked with the Analytical Support Services and Evaluations for Sustainable Systems (ASSESS) to create a 2018 Standards Alliance Work plan and budget across West Africa. ANSI worked with ASSESS and the respective West African USAID missions to determine projects for FY2018 including: Risk-Based Consumer Protection Follow-up Workshops (Senegal, Ghana, Cote d'Ivoire), Workshops with U.S. Investors to Sensitize Stakeholders on International Standards, Textiles and Apparel Technical Training, and U.S. – Cote d'Ivoire, Ghana, & Senegal: Focused TBT NNA/NEP Training.

 Planning for West Africa Training on Textiles and Apparel Standards: Ghana, Cote d'Ivoire, and Nigeria (Year 5 Annual Plan #23)

During this quarter, ANSI worked extensively with the team at Analytical Support Services and Evaluations for Sustainable Systems (ASSESS), national standards bodies, and the respective USAID missions to plan for a West Africa Training on Textiles and Apparel Standards during Q1 2018. The workshop will focus on meeting U.S. textile/apparel standards for export under AGOA, including AATCC and ASTM International standards for woven apparel, dye testing and fabric strength. The workshops will take place in Ghana and Cote d'Ivoire, as well as, in non-Standards Alliance country, Nigeria, through funding from ASSESS.

 Risk-based Consumer Protection Orientation Delegation visit by Senegal, Ghana, and Cote d'Ivoire (Year 5 Annual Plan #19)

On October 10-13, 2017, the Standards Alliance organized a four-day training activity in Washington, DC. The orientation visit covered topics related to "A Risk-Based Approach to Consumer Protection," with the primary goal of helping West African countries strengthen their risk-based consumer protection systems.

The visiting delegation included eight delegates from Cote d'Ivoire, Senegal, and Ghana and one observer from Nigeria. During the delegation visit, 15 public- and private-sector organizations provided detailed presentations that introduced the delegates to various aspects of the U.S. risk-based consumer protection system. The visit also addressed topics related to trade facilitation (including import safety and border measures), standards, conformity assessment, technical regulations (including relevant tests and certifications of imports), and the role of the government and the private sector.

<u>Zambia</u>

 Postponed Activity for Standards in Support of U.S.- Zambia Trade and Investment Workshop (Year 5 Annual Plan #9)

The 2-day, Standards Alliance workshop in Zambia focusing on "Standards to support U.S. – Zambia trade and investment" was postponed due to an unforeseen government conflict in Zambia and further delayed due to a cholera outbreak in January 2018. The original workshop date of December 4 - 5, 2017 in Lusaka, Zambia but is currently being planned for the end of Q1. The focus of the workshop will be "Standards to support U.S. - Zambia trade and investment" and will focus on three critical sectors to the Zambian economy: energy, mining, and agriculture.

EVALUATION OF ACTIVITIES

The primary outcomes for the period of performance are outlined in the table below.

#	Country	Definition	Required in Work Plan?
1	United States	Provided regular project updates and communication to government and private sector stakeholder groups outlined in the project plan	Yes
2	United States	Posted project news and activities to the Standards Alliance website	Yes
3	Indonesia	Water for Indonesia Now – community challenge and accreditation transfer	Yes
4	Colombia, Mexico, Peru and CAFTA-DR	Advanced Medical Technology Association (AdvaMed) landscaping of international Regulatory Coherence benchmarks and completion of Regulatory Coherence (Good Regulatory Design) Policy Guide	Yes
5	West Africa	Risk-Based Consumer Protection Delegation visit to the United States	Yes
6	Southern, East, and West Africa	U.S. Presentation on Sustainable Agriculture Standards at ARSO Conformity Assessment Committee Meeting	No
7	Jordan-Middle East and North Africa (MENA)	IAPMO engagement with JSMO, RSS and MWPH	Yes

This period of performance included a combination of execution and planning for future activities some of which will take place in the final quarter of 2017. The outcomes witnessed in Q4 are positive and represent the continued success of the Standards Alliance program.

In particular, activities carried out through the AdvaMed-led initiative in Latin America have started to gain recognition in the medical device industry and beyond. The Regulatory Coherence Implementation Guideline in English, Spanish and Portuguese has been touted by various U.S. groups including the Americas Business Dialogue (ABD) and its Regulatory Working Group together with its secretariat, the Inter-American Development Bank (IDB). These groups have secured their consensus to have the Summit of the Americas CEOs and Leaders endorse the adoption of Regulatory Coherence policies across the Western Hemisphere at its upcoming April 2018 meeting in Lima, Peru. Further endorsements from key players like the National Institute for Food and Drug Administration (INVIMA) (Colombia), PAHO and the Brazilian Inter-Ministerial Trade Chamber (CAMEX) will be instrumental in ensuring successful implementation of deliverables in Colombia, Mexico, Peru, CAFTA-DR.

CONCLUSION

This period of performance achieved important milestones for the Standards Alliance such as the continued implementation of AdvaMed's work plan with medical device regulators in Latin America, continued development and enforcement of plumbing codes and standards in Indonesia and the formation of the Indonesia Plumbing Association. The Standards Alliance also witnessed significant progress toward completion of the 4th year's activities. ANSI looks forward to building off these successes in the next period and carrying out activities with Mozambique, Zambia, Colombia, Peru, CAFTA-DR and other partners.